

117TH CONGRESS
2D SESSION

S. 5292

To protect and expand access to donor milk, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 15, 2022

Ms. DUCKWORTH introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To protect and expand access to donor milk, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Access to Donor Milk
5 Act of 2022”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

8 (1) The term “donor milk” means human milk
9 that is processed without additives.

10 (2) The term “nonprofit milk bank” means a
11 milk bank that—

1 (A) meets standards established by the
2 Food and Drug Administration for purposes of
3 ensuring the safety of donor milk and milk
4 banks;
5 (B) collects, tests, processes, pasteurizes,
6 and distributes donor milk, in compliance with
7 applicable law; and
8 (C) is described in section 501(c)(3) of the
9 Internal Revenue Code of 1986 (26 U.S.C.
10 501(c)(3)) and exempt from tax under section
11 501(a) of such Code (26 U.S.C. 501(a)).

12 **SEC. 3. FINDINGS.**

13 Congress finds the following:

14 (1) Human milk is the optimal first food for in-
15 fants.

16 (2) Medically vulnerable infants, including those
17 born prematurely and those with congenital or ac-
18 quired conditions, derive significant health benefits
19 from human milk.

20 (3) Mothers of medically vulnerable infants
21 often face unique obstacles to producing enough
22 milk. When a parent's milk is not available, the pro-
23 vision of donor milk improves health outcomes for
24 the infant, including decreasing rates of necrotizing
25 enterocolitis.

1 (4) Nonprofit milk banks provide a critical
2 medical service.

3 (5) The nonprofit milk banking model of col-
4 lecting donor milk from uncompensated donors and
5 accreditation ensures a safe and high-quality prod-
6 uct for the Nation's most vulnerable infants.

7 **SEC. 4. SUPPORT FOR DONOR MILK ACTIVITIES.**

8 Section 17 of the Child Nutrition Act of 1966 (42
9 U.S.C. 1786) is amended—

10 (1) in subsection (b)(4), by inserting “(includ-
11 ing support for donor milk (as defined in section 2
12 of the Access to Donor Milk Act of 2022) activi-
13 ties)” after “promotion”; and

14 (2) in subsection (h)(1)(C)—

15 (A) in clause (i), by striking “clause (ii)”
16 and inserting “clauses (ii) and (iii)”; and

17 (B) by adding at the end the following:

18 “(iii) DONOR MILK.—A State agency
19 may use amounts made available under
20 clause (i) for—

21 “(I) collecting and storing dona-
22 tions of unprocessed human milk;

23 “(II) the transfer of the milk de-
24 scribed in subclause (I) to a nonprofit
25 milk bank; and

1 “(III) making the milk trans-
2 ferred to a nonprofit milk bank under
3 subclause (II) available to program
4 participants at low or zero cost.”.

5 **SEC. 5. EMERGENCY CAPACITY FUNDING FOR MILK BANKS.**

6 (a) IN GENERAL.—The Secretary of Health and
7 Human Services (referred to in this section as the “Sec-
8 retary”) shall award competitive grants, subject to sub-
9 section (f), to eligible entities for expanding emergency ca-
10 pacity with respect to banking donor milk.

11 (b) APPLICATION.—An eligible entity seeking a grant
12 under this section shall submit an application to the Sec-
13 retary at such time, in such manner, and containing such
14 information as the Secretary may require.

15 (c) USE OF FUNDS.— Expanding emergency capacity
16 pursuant to a grant under this section may include—

- 17 (1) publicizing the need for donor milk;
18 (2) providing resources to patients and pro-
19 viding information to clinicians about donor milk;
20 (3) covering donor milk collection, storage,
21 transfer, and processing fees;
22 (4) increasing staffing and supplies needed at
23 nonprofit milk banks; and
24 (5) purchasing consumable products needed for
25 donor milk processing.

1 (d) ELIGIBLE ENTITY.—For purposes of this section,

2 the term “eligible entity” means an entity that—

3 (1) is a nonprofit milk bank accredited by an
4 accrediting body recognized by the Food and Drug
5 Administration; and

6 (2) in the application submitted under sub-
7 section (b), demonstrates, with respect to such enti-
8 ty—

9 (A) a rapid increase in demand for donor
10 milk; or

11 (B) a shortage of supplies needed to oper-
12 ate a nonprofit milk bank.

13 (e) AUTHORIZATION OF APPROPRIATIONS.—For the
14 purposes of carrying out this section, there are authorized
15 to be appropriated \$3,000,000 for fiscal year 2023, and
16 such sums as may be necessary for each fiscal year there-
17 after.

18 (f) CRITERIA.—The Secretary may award grants
19 under subsection (a) only in the event of any of the fol-
20 lowing:

21 (1) The Secretary determines that expanded ca-
22 pacity is necessary to respond to any major disaster
23 declared by the President under section 401 of the
24 Robert T. Stafford Disaster Relief and Emergency
25 Assistance Act (42 U.S.C. 5170).

1 (2) The Secretary determines that Federal as-
2 sistance is needed to supplement State and local ef-
3 forts and capabilities to save lives and to protect
4 property and public health and safety, or to lessen
5 or avert the threat of a catastrophe in any part of
6 the United States.

7 (3) The Secretary determines emergency capac-
8 ity is needed to ensure adequate supply is available
9 to meet the demand for donor milk from a nonprofit
10 donor milk bank.

11 **SEC. 6. DONOR MILK AWARENESS PROGRAM.**

12 (a) CHILD NUTRITION.—The Child Nutrition Act of
13 1966 (42 U.S.C. 1771 et seq.) is amended by adding at
14 the end the following:

15 **“SEC. 24. DONOR MILK AWARENESS PROGRAM.**

16 “(a) DEFINITION OF DONOR MILK.—In this section,
17 the term ‘donor milk’ has the meaning given the term in
18 section 2 of the Access to Donor Milk Act of 2022.

19 “(b) ESTABLISHMENT.—The Secretary shall estab-
20 lish a donor milk awareness program (referred to in this
21 section as the ‘program’)—

22 “(1) to educate the public on donor milk and
23 nonprofit milk banks; and

24 “(2) to publicize the need for donor milk to be
25 provided to nonprofit milk banks.

1 “(c) CONDUCT OF PROGRAM.—In carrying out the
2 program, the Secretary may—

3 “(1) develop, or assist other entities to develop,
4 appropriate educational materials, including public
5 service announcements, promotional publications,
6 and press kits, for the program;

7 “(2) publish information about the program on
8 the website of the Department of Agriculture; and

9 “(3) distribute, or assist other entities to dis-
10 tribute, such materials, as appropriate, to public and
11 private individuals and entities.

12 “(d) COOPERATIVE AGREEMENTS.—The Secretary
13 may enter into cooperative agreements with Federal agen-
14 cies, State and local governments, and other entities to
15 carry out the program.

16 “(e) AUTHORIZATION OF APPROPRIATIONS.—For
17 purposes of carrying out the program, there is authorized
18 to be appropriated \$1,000,000 for fiscal year 2023.”.

19 (b) HHS PUBLIC AWARENESS CAMPAIGN WITH RE-
20 SPECT TO DONOR MILK FROM NONPROFIT MILK
21 BANKS.—

22 (1) IN GENERAL.—The Secretary of Health and
23 Human Services shall develop a public awareness
24 campaign with respect to donor milk from nonprofit
25 milk banks.

10 SEC. 7. CLARIFYING THE REGULATORY STATUS OF DONOR 11 MILK.

12 (a) IN GENERAL.—Not later than 1 year after the
13 date of the enactment of this Act, the Secretary of Health
14 and Human Services shall issue guidance to clarify the
15 regulatory status (and any associated categorization) of
16 donor milk provided by a nonprofit milk bank.

17 (b) REPORT.—Not later than 180 days after the date
18 of the enactment of this Act, the Secretary of Health and
19 Human Services shall submit to Congress a report regard-
20 ing the issuance of guidance on the categorization of donor
21 milk provided by a nonprofit milk bank under the rule
22 issued under subsection (a).

